K132910

510(k) Summary

DEC 16 2013

Submitter:	Synthes Spine 1302 Wrights Lane East West Chester, PA 19380
Contact Person:	Eugene Bang Regulatory Affairs Associate Telephone: (508) 977-3966 Fax: (508) 828-3797
Date Prepared:	November 25, 2013
Trade Name:	DePuy Synthes Spine Dens Access System
Device Class:	Class II
Product Code(s):	HWC
Common Name:	Screw, Fixation, Bone
Classification Name:	Smooth or Threaded Metallic Bone Fixation Fastener
Regulation Number:	21 CFR 888.3040
Predicate Devices:	Synthes 4.0mm Cannulated Screw – K963192 HBS Headless Bone Screw – K020791 Headless Compression Screw – K112672
Device Description:	DePuy Synthes Spine Dens Access System is comprised of screws and instruments. The screws are available in multiple lengths and will be offered non-sterile. The screws feature self-drilling, self-tapping tips, reverse cutting flutes and cancellous threads.
Indications:	For fracture fixation of small bones and small bone fragments including odontoid fractures.
Materials:	Manufactured from Titanium-6Aluminum-7Niobium Alloy conforming to ASTM F-1295.

K132910

Comparison to Predicate Device:

The substantial equivalence of the subject device to the predicates indentified above is based upon the equivalence of intended use, design (fundamental scientific technology), materials, performance, sterility, and biocompatibility.

Non-clinical Test Summary:

Mechanical testing was provided in order to provide data to support a substantial equivalence determination. These tests were performed to characterize the properties and functionality of the screw, as well as to allow comparison with established acceptance criteria.

The following mechanical tests were conducted on the screw:

- Torque to failure test
- Cantilever bend test
- Pull-out strength test
- Insertion torque test

Clinical Test Summary:

No clinical data was necessary to demonstrate substantial equivalence, nor safety and effectiveness of this system.

Conclusion:

Based on the predicate comparison and testing, it is the opinion of Synthes that the proposed screw is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 16, 2013

Synthes (USA) Products, LLC
Mr. Eugene Bang
Regulatory Affairs Associate
1302 Wrights Lane East
West Chester, Pennsylvania 19380

Re: K132910
Trade/Device Name: DePuy Synthes Spine Dens Access System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: September 23, 2013
Received: September 24, 2013

Dear Mr. Bang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K132910

Device Name: DePuy Synthes Spine Dens Access System

Indications For Use:

For fracture fixation of small bones and small bone fragments including odontoid fractures.

Prescription Use ____X_____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices